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Alberto Bianco

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EXAMINER

GREENE, IVAN A

ART UNIT

PAPER NUMBER

4161

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/553,439 | <b>Applicant(s)</b><br>BIANCO ET AL. |  |
|                              | <b>Examiner</b><br>IVAN GREENE       | <b>Art Unit</b><br>4161              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 27-52 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Examiner notes claims 1-26 have been canceled by Applicant. Claims 27-52 are the subject of this action.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Group I, claim(s) 27-32 and 45, drawn to a protected functionalized carbon nanotube.
2. Group II, claim(s) 33-36, drawn to a deprotected functionalized carbon nanotube.
3. Group III, claim(s) 37 and 38, drawn to a method of making a protected functionalized carbon nanotube.
4. Group IV, claim(s) 39-44, drawn to a method of making a deprotected functionalized carbon nanotube.
5. Group V, claim(s) 46, drawn to a pharmaceutical composition comprising a functionalized carbon nanotube.
6. Group VI, claim(s) 47 and 48, drawn to a method of drug delivery using a functionalized carbon nanotube.

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7. Group VII, claim(s) 49, drawn to a method of preparing an immunological.

8. Group VIII, claim(s) 50, drawn to a method of treatment.

9. Group IX, claim(s) 51, drawn to a method of preparation of functionalized surfaces.

10. Group X, claim(s) 52, drawn to a method of preparation of electrochemical biosensors.

1. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions." Moreover, as stated in Rule 13.2 PCT, Unity of Invention is satisfied "where a group of inventions is claimed in one and the same international application, the requirement of unity referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features."

2. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole makes over the prior art so linked as to form a single general inventive concept." A functionalized carbon nanotube, with homogenously surface substituted reactive groups being substantially intact and soluble in organic and/or aqueous solvents, does not present a contribution over the prior art, as it is disclosed, and therefore anticipated, in US Patent No. 6,203,814 B1 (hereafter referred to as '814). '814 discloses fullerenes which are functionalized by chemical substitution or by absorption of functional moieties wherein the functional moieties are uniformly or non-uniformly substituted on the

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surface (Abstract). '814 further discloses' "...the carbon fibrils are processed prior to contacting them with the functionalizing agent...Such processing may include dispersing the fibrils in a solvent. " (col. 8, line 12). '814 further discloses, "Typically, such fibrils are substantially cylindrical, graphitic nanotubes of substantially constant diameter and comprise cylindrical graphitic sheets..." (col. 2, line 21). As a result, as currently presented, claim 1 does not possess a special technical feature and, as such, unity between the above Groups I-X is broken.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- a. The disease of claim 50 (cancer, autoimmune or infectious).

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b. The carbon nanotubes of claim 28 (single-walled (SWNT's) or multi-walled (MWNT's)).

c. The functionalized carbon nanotube of claims 27-52.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

Claim 50 reads on the species: disease (cancer, autoimmune or infectious). Claims 28-52 read on the species: carbon nanotube (single-walled (SWNT) or multi-walled carbon nanotubes (MWNT)). Claims 46-52 read on the species: a functionalized carbon nanotube.

Applicants must elect a single exact carbon nanotube (SWNT or MWNT). Should Applicant elect inventions 5-10 a single exact functionalized carbon nanotube must be chosen. Should Applicant elect invention 8, a single exact disease must be chosen.

The following claim(s) are generic: claim 50 is generic to the disease (cancer, autoimmune or infectious); claims 28-52 are generic to carbon nanotube (SWNT or MWNT); claims 46-52 are generic to a functionalized carbon nanotube.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

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corresponding special technical features for the following reasons: the disease classes represent non-overlapping subject matter wherein the patient populations are different.

7. Examiner notes claims 47-49, 51 and 52 recite --the use of-- where no positive method steps are recited. If Applicant chooses a group which includes said claim(s), Applicant is advised to amend the claim(s) to include specific process steps compliant with the provisions U.S.C 112 for examination on the merits. See MPEP 2173.05(q).

8. Regardless of the election Applicants make, Applicant is advised that, if necessary, the claims should be amended to proper independent form for examination on the merits.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IVAN GREENE  
Examiner, Art Unit 1616

/John Pak/  
Primary Examiner, Art Unit 1616